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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,558	04/21/2004	Randell L. Mills	62248-1	5441
20736 7590 03/17/2008 MANELLI DENISON & SELTER 2000 M STREET NW SUITE 700 WASHINGTON, DC 20036-3307				
EXAMINER				
POWERS, FIONA				
ART UNIT		PAPER NUMBER		
1626				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/828,558

**Applicant(s)**

MILLS ET AL.

**Examiner**

Fiona T. Powers

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35, 37-176, 178-181, 228 and 229 is/are pending in the application.
- 4a) Of the above claim(s) 39-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35, 37, 38, 71-176, 178-181, 228 and 229 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-849)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Receipt is acknowledged of the amendment filed November 29, 2007, which has been entered in the file.

Claims 39 to 70 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 5, 2006.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It does not identify the citizenship of each inventor.  
The citizenship of inventor Guo-Zhang Wu is not listed.

Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 24 is not a further limitation of claim 1 when the chemiluminescent molecule comprises the structures set forth in claim 24 except for Aminophthalhydrazide because A in claim 1 must comprise a phthalhydrazide. The other structures set forth

in claim 24, for example 2,6-diaminopyrene, Dioxene or Imidazole derivatives, do not comprise a phthalhydrazide.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 to 35, 37, 38, 71 to 176, 178 to 181, 228 and 229 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 to 35, 27, 38, 71 to 176, 178 to 181, 228 and 229 are indefinite because the compound of the formula A-B-C cannot be synthesized when the steps comprise 1) forming a benzophenone, 2) forming a diaryl ethylene and at least one of steps (a) through (g). For example if steps 1), 2) and step (a) or (b) or (d) or (e) is performed how is A (a phthalhydrazide) attached and how is C attached? If the steps comprise 1), 2) and step (c) or (f) is performed how is C attached? If the steps comprise 1), 2) and step (g), how is B attached?

Throughout the claims the terms "comprises" and "comprising" renders the claims indefinite. It is not clear

what else the compound or dye can comprise. See claims 28 to 30, 34, 37, 79, 80, for example.

Throughout the claims the terms "derivative", "analog" and "analogue" render the claims indefinite because it is not clear what compounds are intended.

Claim 2 is indefinite because in claim 2, the compound serves to delivery the C moiety to a desired biological compartment but claim 1 is directed to a method of synthesis of A-B-C not a method of delivering C to a biological compartment.

In claim 24, R, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub> and X are not defined. In claim 24, "and" should be inserted between the last two structures listed.

In claim 30, R is not defined for the dyes at the bottom of page 41. Also, in claim 30 it is not clear what the numbers that are shown opposite the dyes Malachite Green through Acid Green 50 on pages 9 to 12 refer to. Claim 30 further defines the cationic dye but it contains reactions, for example on pages 19 and 42. The reactants should be deleted so that only the cationic dye is shown. In claim 30, "and" should be inserted between the last two structures listed.

In claim 35, "and" should be inserted between the last two structures listed.

In claims 73 to 77 it is not clear what "functional groups" are represented by  $R^1$ ,  $R^2$  and/or  $R^3$ .

In claim 85, there is no antecedent basis in claim 84 for the "amino-substituted aryl groups".

In claim 91, "protecting" should be -protected-.

Claims 153, 155 and 163 show a negative charge without specifying what the anion is.

Claims 167 to 170 do not disclose the step for how C is attached. It only describes how to make A-B.

In claim 172, B is not defined.

Claim 228 is indefinite because it improperly incorporates by reference essential subject matter. See the books recited at the bottom of page 115.

not defined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 to 35, 37, 38, 71, 72, 81 to 103, 105 to 127, 131 to 146, 148 to 152, 157 to 160, 165 to 171, 173 to 180, 228 and 229 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of

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synthesis of a compound A-B-C wherein A is a chemiluminescent moiety that is a phthalhydrazide, sulfonyloxamide or active oxalate, B is an energy acceptor moiety that is a 1,5-diarylpentadiene and C is Foscarnet, ddc or acycloguanosine, does not reasonably provide enablement for a method of synthesis of a compound A-B-C where A is any chemiluminescent moiety, B is any energy acceptor moiety and C is any biologically active moiety for example, any pharmaceutical or drug. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph are as follows:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of skill in the art.

See In re Wands, 8 USPQ2d 1400.

In the instant case, there is unpredictability in the art and the breadth of the claims encompasses a method of synthesis of a very large group of compounds of the formula A-B-C where A is any chemiluminescent moiety, B is any energy acceptor moiety and C is any biologically active moiety for example, any pharmaceutical or drug. The working examples in the specification are only directed to a method of synthesis of a compound A-B-C wherein A is a chemiluminescent moiety that is a phthalhydrazide, sulfonyloxamide or active oxalate, B is an energy acceptor moiety that is a 1,5-diarylpentadiene and C is Foscarnet, ddc or acycloguanosine. It would require an undue amount of experimentation for one of skill in the art to synthesize the entire scope of compounds encompassed by formula A-B-C as different reactions and reaction conditions would be required.

Applicant's arguments filed November 29, 2007 have been fully considered but they are not persuasive. Applicants state that the Examiner has improperly ignored the written description and focused on the experimental examples. Applicants point to the Summary of the Invention and parts of the specification wherein possible candidates for A, B and C are given. The Summary of the Invention discloses what A-B-C, D-A-B-C, A-D-B-C is but does not disclose how to prepare them. The list of



candidates for A, B, and C also does not describe how to prepare A-B-C.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Fiona T. Powers/  
Primary Examiner, Art Unit 1626

Fiona T. Powers  
Primary Examiner  
Art Unit 1626

ftp  
March 3, 2008